SEP 1 2 2002

1C022724

510(k) Summary

Submitter

LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, CA 95035
Contact: John E. Hughes
Date Prepared: August 12, 2002

Device Name

SURESTEP® Blood Glucose Monitoring System
Common name: Glucose test system

Predicate Device

SURESTEP Blood Glucose Monitoring System

Device Description

The LifeScan SURESTEP Blood Glucose Monitoring System consists of a glucose reagent test strip, a reflectance photometer, and a quality control solution. A lancing device and lancets are also included with the system. The user obtains a blood sample and applies it to the test strip before inserting the strip into the meter. The user obtains a blood sample and applies it to the test strip before inserting the strip into the meter. After inserting the strip into the meter, the glucose value displays on the meter's liquid crystal display (LCD). The test strip color can be compared visually to a color chart provided with the system to estimate if the glucose concentration is very high or very low as a backup to the meter.

When blood is placed on the test strip, glucose in the blood sample reacts with oxygen to yield gluconic acid and hydrogen peroxide. This reaction is catalyzed by the enzyme glucose oxidase present in the test strip. Hydrogen peroxide then reacts with the indicator dye, catalyzed by the presence of peroxidase in the test strip, creating a blue color proportional to the concentration of glucose present in the blood sample. An absorbent layer in the test strip acts as a reservoir for excess blood.

The blood glucose meter is a reflectance photometer that measures the light reflectance of the blue color that develops on the test strip. The meter electronically converts the reflectance data to a digital result that is displayed on a liquid crystal display (LCD). The meter is powered by two 1.5 V AAA alkaline batteries. The user calibrates the meter for each lot number of test strips in use by entering a calibration code specific to that lot number. A quality control solution is included in the system so that the user can check system performance.

Intended Use

The SURESTEP System is for quantitative measurement of glucose in whole blood. It may be used by persons with diabetes in the home and by healthcare professionals in clinical settings as an aid to monitor effectiveness of diabetes control.

Comparison to Predicate Device

The existing labeling of SURESTEP® Blood Glucose Monitoring System has been reformatted and simplified to increase understanding and provide clear explanations of the performance capabilities and the performance limitations of the system. In addition, the visual backup system has been modified by eliminating comparison colors equivalent to 100 mg glucose/dL and 180 mg glucose/dL.

Conclusion

The modified SURESTEP Blood Glucose Monitoring System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 12 2002

Mr. John E. Hughes
Manager, Regulatory Submissions
LifeScan, Inc.
1000Gibraltar Drive
Milpitas, CA 95035-6312

Re: k022724
Trade/Device Name: SureStep Blood Glucose Monitoring System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: August 15, 2002
Received: August 16, 2002

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K022724

Device Name: **SURESTEP Blood Glucose Monitoring System**

Indications for Use:

The SURESTEP System is for quantitative measurement of glucose in whole blood. It may be used by persons with diabetes in the home and by healthcare professionals in clinical settings as an aid to monitor effectiveness of diabetes control.

for Dr Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022724

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-the-Counter Use ✓
(Per 21 CFR 801.109)